Application No. 10/634,331 Applicant: Alan J. POLITO et al.

AMENDMENT TO THE CLAIMS

What is claimed is:

Claims 1-97 (Canceled)

98. (Currently amended) An apparatus <u>useful</u> for conducting a lateral flow assay on a test strip for detection detecting the addition of an analyte in a sample to a test strip in a lateral flow assay comprising:

a housing having a receptacle for retaining a test strip for a lateral flow assay; and an autostart means;

wherein the autostart means comprises a capacitance sensor that senses application of a sample or buffer to the test strip when the test strip is placed in the receptacle, and initiates timing of the assay, such that the analyte is detected by analysis of reflectance data from one or more sectors of the test strip performed by the apparatus.

- 99. (Currently amended) The apparatus of claim 98, further comprising a heating element <u>positioned</u> position to lie under and contact the test strip when the test strip is in place.
 - 100. (Canceled)
- 101. (Previously presented) The apparatus of claim 98, further comprising a test strip.
- 102. (Previously presented). The apparatus of claim 101, wherein the test strip contains a biological sample.
- 103. (Previously presented) The apparatus of claim 102, wherein the biological sample is selected from the group consisting of whole blood, serum, plasma, and urine.

1-SF/7324703.1 2

Application No. 10/634,331

Applicant: Alan J. POLITO et al.

104. (Previously presented) The apparatus of claim 102, wherein the biological sample is a human biological sample.

- 105. (Previously presented) The apparatus of claim 102, wherein the biological sample is a non-human biological sample.
- 106. (Previously presented) The apparatus of claim 105, wherein the non-human biological sample is a sample consisting of a livestock and a food product.
- 107. (Withdrawn) An apparatus for conducting lateral flow assay on a test strip for detection of an analyte in a sample comprising:

a housing having a receptacle for retaining a test strip for a lateral flow assay;

an autostart means;

a test strip comprising an internal quality control means; wherein the autostart means senses application of sample or buffer to the test strip when the test strip is placed in the receptacle, and initiates timing of the assay.

- 108. (Withdrawn) The apparatus of claim 107, wherein the internal quality control means of the test strip comprises a first control measurement zone including a first control agent immobilized therein which is capable of binding the control agent; the first control agent being in mathematical relationship with the second control agent.
- 109. (Withdrawn) The apparatus of claim 107, further comprising a detection means for detecting reflectance of the test strip.
- 110. (Withdrawn) The apparatus of claim 107, further comprising a heating element positioned to lie under and contacts the test strip.

Application No. 10/634,331 Applicant: Alan J. POLITO et al.

- 111. (Withdrawn) The apparatus of claim 107, wherein the detection of the analyte includes quantitation of the analyte.
- 112. (Withdrawn) A method of detecting an analyte in a sample by use of a lateral flow assay on a test strip comprising the steps of:
 - (a) providing a sample on a test strip;
- (b) allowing an analyte in the sample, if present, to react with an analyte binding agent on the test strip to form a complex;
- (c) measuring reflectance of the test strip after formation of the complex; (d) detecting background reflectance; and (e) determining amount of analyte present.
- 113. (Withdrawn) The method of claim 112, wherein the method comprises use of a software program to effect one or more of the steps.
- 114. (Withdrawn) A method of analyzing results of a lateral flow assay on a test strip for detection of an analyte, wherein the test strip comprises a first control measurement zone a second control measurement zone, and an analyte binding zone, comprising the steps of:
 - (a) determining reflectance of the test strip;
 - (b) generating a baseline reflectance;
 - (c) quantifying measurement zones with respect to the baseline; and
- (d) comparing measurement zones corresponding to the control binding zones and analyte binding zone.
- 115. (Withdrawn) The method of claim 114, wherein the baseline is generated after the analyte, if present, has been allowed to react with an analyte bind agent in the analyte binding zone.
- 116. (Withdrawn) A method of conducting quality control on a test strip for a lateral flow assay comprising the steps of:

Application No. 10/634,331 Applicant: Alan J. POLITO et al.

- (a) detecting a first reflectance of a first control zone containing a first control binding agent bound to a control agent;
- (b) detecting a second reflectance of a second control zone containing a second control binding agent bound to the control agent; and
- (c) determining a mathematical relationship between the first reflectance and the second reflectance to determine if the mathematical relationship is within a specified range.

1-SF/7324703.1 5